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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/276,820	03/26/99	HARRINGTON J	1522.0030004

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EXAMINER	
SHUKLA,R	
ART UNIT	PAPER NUMBER
1632	5

DATE MAILED: 09/27/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/276,820	Harrington et al
Examiner	**Group Art Unit**
Ram Shukla	1632

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-7, 10-15, 20-36, and 58-231* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-7, 10-15, 20-36, and 58-231* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims 1-7, 10-15, 20-36 and 58-231 are pending in the instant application

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 10-12, 15, 20-24, 28-29, 85, 86, 128, 159, 161-162, 164-167, 169-175, 177-183, and 214, drawn to a vector and uses thereof, classified in class 435, subclass 320.1.

II. Claims 5-7, 13-14, 20-24, 28-29, 85, 128, 159, 161-162, 164-167, 169-175, 177-183, and 227, drawn to a vector and uses thereof, classified in class 435, subclass 320.1.

III. Claims 1-4, 10-12, 15, 20-24, 28-29, 85, 86, 128, 159, 161-162, 164-167, 169-175, 177-183, and 214, drawn to a vector and uses thereof, classified in class 435, subclass 320.1.

IV. Claims 5-7, 13-14, 20-24, 28-29, 85, 128, 159, 161-162, 164-167, 169-175, 177-183, and 227, drawn to a vector and uses thereof, classified in class 435, subclass 320.1.

V. Claims 30-35, drawn to primers, classified in class 536, subclass 24.33.

VI. Claims 36, drawn to a method of DNA synthesis, classified in class 435, subclass 91.3.

VII. Claims 58, 59, 64-69, 71-74, 76-82, 85-123, 128, 129, 130-132, 157, 159, 161-162, 164-167, 169-175, 177-183, and 223-226, drawn to a vector and uses thereof, classified in class 435, subclass 320.1.

VIII. Claims 60, 63-86, 99-115, 128, 130-132, 197, 203, and 223-224, drawn to a vector and uses thereof, classified in class 435, subclass 320.1.

IX. Claims 61, 63-86, 99-115, 128, 130-132, and 223-224, drawn to a vector and uses thereof, classified in class 435, subclass 320.1.

X. Claims 62-82, 99-115, 128,130-132, 159, 161-162, 164-167, 169-175, 177-183, and 223-224, drawn to a vector and uses thereof, classified in class 435, subclass 320.1.

XI. Claims 124-127, and 129, drawn to a method of enhancing gene expression, classified in class 435, subclass 455.

XII. Claims 133-137, drawn to a method of identifying cells, classified in class 435, subclass 455.

XIII. Claims 138-144, 149-153, 157-188, 191-195, 198, 200-202, 204, 215-217 and 221, drawn to a vector and uses thereof, classified in class 435, subclass 320.1.

XIV. Claims 145-148, 159-183, 186-188, 191-195, 198, 200-202, 204, and 215-216, drawn to a vector and uses thereof, classified in class 435, subclass 320.1.

XV. Claims 154-156, 159-183, 186-188, 191-195, 198, 200-202, and 204, drawn to a vector and uses thereof, classified in class 435, subclass 320.1.

XVI. Claims 189-190, 196, 199, and 203, drawn to a method of gene expression, classified in class 435, subclass 455.

XVII. Claims 205-213, 218-220, and 221-222, drawn to a method of gene expression, classified in class 435, subclass 455.

XVIII. Claims 228-231, drawn to a method of drug discovery, classified in class 435, subclass 375.

3. Claims 1-4, 10-12 and 15 are generic to groups I and III. Should any of these groups be elected, claims 1-4, 10-12, and 15 will be examined to the extent they encompass the elected invention.

4. Claims 5-7 and 13-14 are generic to groups II and IV. Should any of these groups be elected, claims 5-7 and 13-14 will be examined to the extent they encompass the elected invention.

5. Claims 20-24 and 28-89 are generic to groups I - IV. Should any of these groups be elected, claims 20-24 and 28-89 will be examined to the extent they encompass the elected invention.

6. Claim 85 is generic to groups I-IV and VII-IX . Should any of these groups be elected, claim 85 will be examined to the extent it encompasses the elected invention.

7. Claim 86 is generic to groups I, III and VII-IX . Should any of these groups be elected, claim 86 will be examined to the extent it encompasses the elected invention.

8. Claim 128 is generic to groups I-IV and VII-X . Should any of these groups be elected, claim 128 will be examined to the extent they encompass the elected invention.

9. Claims 130-132 are generic to groups VII - X. Should any of these groups be elected, claims 130-132 will be examined to the extent they encompass the elected invention.

10. Claims 159, 161-162, 164-167, 169-175, and 177-183 are generic to groups I - IV, VII and X. Should any of these groups be elected, claims 159, 161-162, 164-167, 169-175, and 177-183 will be examined to the extent they encompass the elected invention.

11. Claim 214 is generic to groups I and III . Should any of these groups be elected, claim 214 will be examined to the extent it encompasses the elected invention.

12. Claim 227 is generic to groups II and IV . Should any of these groups be elected, claim 227 will be examined to the extent it encompasses the elected invention.

13. Claims 64-69, 71-74, 76-82, 85-86, 99-115, and 223-224 are generic to groups I - IV, VII and X. Should any of these groups be elected, claims 64-69, 71-74, 76-82, and 99-115 will be examined to the extent they encompass the elected invention.

14. Claims 63, 70, 75, and 83--84 is generic to groups VIII -X . Should any of these groups be elected, claims 63, 70, 75, and 83-86 will be examined to the extent they encompass the elected invention.

15. Claims 159-183, 186-188, 191-195, 198, 200-202, and 204 are generic to groups XIII-XV. Should any of these groups be elected, claims 159-183, 186-188, 191-195, 198, 200-202, and 204 will be examined to the extent they encompass the elected invention.

16. The inventions are distinct, each from the other because of the following reasons:

The inventions of the groups I-IV VII-X, and XIII-XV are all directed to different vectors, host cell comprising such vectors, in-vivo and in-vitro methods of gene expression, methods of modulating gene expression using such vectors and methods of producing candidate proteins. However, all these vectors are patentably distinct because they are comprised of different sequence elements, that would result in a different pattern and/or different levels of gene expression and that would work by different mechanisms and may have different utilities. Therefore, each element would require a different search in the non-patent literature. For example, the invention of group I is drawn to a vector that is comprised of two promoters and two splice donor sites, and such a vector can be used to regulate the expression of two different coding sequences. The vector of the group II is drawn to a vector that is comprised of only one promoter and one exon sequence and therefore, its mode of function and utility would be different from that of the vector of group I. Groups III and IV are related to groups I and II respectively, because they have the same sequence elements, however, they are patentably distinct because they can be used in plant hosts and animal hosts which require independent and distinct regulatory sequence elements and necessary cellular cofactors. For example, the promoter for a plant gene may not function in an animal cells due to lack of or presence of characteristic sequence elements. Therefore, the inventions of the groups I-IV are patentably distinct each from the other and would require separate searches, for example, in the non-patent literature.

The vectors of the groups VII-X and XIII-XV are patentably distinct each from the other and also from the vectors of the groups I-IV because they are comprised of different sequence elements that would regulate the expression of a candidate gene in a certain way. For example, the vector of group VII is drawn to a vector that is comprised of sequence elements for a transcriptional regulatory sequence, a splice donor site, an amplifiable marker, but, it lacks any targeting sequences that can produce homologous recombination. On the other hand, the vector of group VIII is comprised of sequence elements for a promoter (transcription regulatory sequence), a translation codon, a secretion signal sequence, an epitope tag, and splice donor site. Therefore, the vector of group VIII can be used for purification of a candidate gene using

the epitope tag or it can be secreted whereas the vector of group VII can not be. The vector of group IX, in addition to the elements of the group VIII, also contains a protease site that would help in producing a candidate gene as a fusion protein of a marker protein. The candidate protein can be clipped off from the indicator protein to obtain pure candidate protein. The vector of group X lacks an epitope tag or a selection marker or a protease site but contains a signal peptide sequence that by itself is unable to function as a signal peptide, but when joined to an exon due to RNA splice can produce an active signal peptide. The vector of group XIII is comprised of two promoters, of which, one promoter is operably linked to an exon and a splice donor site and the other promoter directs the expression of a selectable marker, on the other hand, the vector of group XIV is comprised of only one promoter but it has a positive and a negative selection marker. The vector of group XV is composed of two promoters but it has two exons two splice donor sites, one exon and splice donor site is under the control of first promoter and the second exon and splice donor site is under the control of the second promoter. As discussed above different sequence elements would result in different expression pattern as well as the mechanism of function of the vectors. Therefore, the vectors of the groups I-IV, VII-X, and XIII-XV are patentably distinct each from the other for the reasons given above, and their analysis would require different searches in the non-patent literature.

The inventions of the groups V and VI are drawn to primers and a method of DNA synthesis, respectively and are patentable distinct from each other because primers of group V can be used for more than one purpose, one of them may a method of DNA synthesis, but primers can also be used a probes in hybridization or in mobility shift assays to identify new sequence elements. The invention of group V is patentably distinct from the inventions of each of the groups I-IV and VII-X, XIII, and XIV, because the sequence structure of a primer and a vector is different, for example, a primer lacks regulatory sequences required for expression in a cell, whereas vectors are characterized by sequence elements that regulate the expression of a coding sequence in a cell. Therefore, the inventions of V and VI will require separate searches in the non-patent literature.

The inventions of the groups VI and XVI-XVII are drawn to different methods and are patentably distinct each from the other because they are drawn to different methods that would

have different steps. For example, the method of enhancing the expression of an endogenous gene, the invention of the group XI, would depend on the type of the vector and the regulatory elements the vector, such as the enhancer element, its tissue specificity or cell type specificity to regulate gene expression. Similarly, the method of identifying a candidate gene, the invention of group XII, would depend on the transcriptional regulatory sequence to direct the expression of the sequence as a given subcellular site and other sequence elements that would regulate the expression of the candidate gene. The steps of a method for DNA synthesis, the invention of the group VI, would be different from those of the method of producing a gene product by transposition. Likewise, the method of producing a protein also depends on the type of vector and what sequence element a vector has. For example, the vector used in the method of the invention of group XVII contains genomic fragment of a gene encoding a protein, in addition to exon and splice donor sites that are heterologous to the candidate protein. Similarly, the method of drug screening or drug discovery, the invention of the group XVIII, will depend, not only the assay system, host cell used as well as the candidate used, it will also depend on the nature of the candidate drugs being screened in the assay. Furthermore, the methods of the groups VI and XVI-XVIII can not be used for the same purpose. Therefore, the analysis of the inventions of the groups VI and XVI-XVIII will require different searches in the non-patent literature.

17. The inventions of each of the groups I-V, VII-X, and XVI-XVIII are also patentably distinct from the methods of each of the groups VI, XI-XII, and XVI-XVIII because the inventions of the groups I-V, VII-X, and XVI-XVIII are drawn to compositions whereas the inventions of the groups VI, XI-XII, and XVI-XVIII are drawn to methods. The methods of the groups VI, XI-XII, and XVI-XVIII can not be used for making the compositions of the groups I-V, VII-X, and XVI-XVIII. Additionally, the compositions of the groups I-V, VII-X, and XVI-XVIII have other utilities than those for practicing the methods of the groups VI, XI-XII, and XVI-XVIII. Therefore, analysis of the groups I-XVIII would require separate searches, for example, in the non-patent literature.

18. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their recognized divergent subject matter, and because each

invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Stanton, can be reached on (703) 308-2801. The fax phone number for this Group is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 305-0196.

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